

Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 16 claims. Due to a restriction requirement, all of these except for claims 6, 7 and 12 were withdrawn. In the present response, Applicant has cancelled all of the originally filed claims and has replaced them with new claims 17-29.

II. The Amendments

Claims to peptides were amended so that they no longer specify a peptide 23 amino acids in length which "has" a particular sequence. The Office Action suggests that such claims are inappropriate because the term "has" is considered to be open-ended, *i.e.*, equivalent to "comprising." Amended claims 17-23 use the transitional phrase "consisting essentially of" and no longer specify that peptides must be 23 amino acids long. Other claims (*i.e.*, claims 24-29) use the transitional phrase "consisting of." Support for all of the new claims may be found in the claims that have been cancelled.

Additional support for claims 20-23 and 26-29 may be found on page 4 of the specification, lines 7-22. This section defines "therapeutically effective amount," recites dosages of 0.01-10 mg of peptide, and suggests that compositions may be administered parenterally for the treatment of stroke, heart attack, spinal injury and prior to surgery.

None of the amendments made herein add new matter to the application, and their entry is therefore respectfully requested.

III. Submission of Declaration

On page 2 of the Office Action, the Examiner indicates that the Declaration submitted with the application is defective because it is not signed. In response, Applicant submits that an executed Declaration identifying the present application by serial number was filed on

August 19, 2002 in response to a "Notice to File Missing Parts of Application – Filing Date Granted." As evidence of this, Applicant is submitting herewith a receipt date-stamped by the Patent and Trademark Office indicating that an executed Declaration was filed. Also attached is a copy of the Declaration itself.

In light of the above considerations, Applicant submits that a properly executed Declaration has previously been submitted. It is therefore respectfully requested that the Examiner's objection be withdrawn.

The Rejections

On pages 2 and 3 of the Office Action, the Examiner rejects claims under 35 U.S.C. § 112, second paragraph. Claim 6 is rejected as being indefinite because it is directed to a peptide 23 amino acids in length which "has" a particular sequence. The Examiner suggests using the transitional phrase "consists of." In response, Applicant has amended claims so that they no longer contain open-ended claim language in combination with a specified peptide length of 23 amino acids. Claims 17 and 18 use the transitional phrase "consisting essentially of" which is narrower than "comprising," but broader than "consisting of." Claims 24 and 25 use the transitional phrase "consisting of" as suggested by the Examiner. In light of these changes, Applicant submits that the Examiner's rejection has been obviated. It is therefore respectfully requested that this rejection be withdrawn.

On page 3 of the Office Action, the Examiner also rejects claims 7 and 12 as being indefinite because they are dependent upon non-elected claims. The present amendments correct this error.

Claim 12 is also rejected based upon the allegation that it is indefinite because pharmaceutical compositions require the presence of at least two components such as a

carrier. The claim is also alleged to be indefinite because it requires a “unit dosage form” but does not define the particular disease for which the dosage form is being administered.

In response, the amended claims are directed to pharmaceutical compositions in which both a peptide and a pharmaceutically acceptable carrier are present (see claims 20 and 26). Thus, the claims require that these compositions have two components and the Examiner’s rejection has therefore been partially obviated.

Applicants do not agree that that term “unit dosage form,” as used in the present claims, is indefinite. This term is defined on page 3 of the application, line 34 – page 4, line 5. It refers to a single drug administration entity such as a tablet, capsule, vial, etc. and is used to distinguish the present compositions from compositions in bulk form. With respect to the amount of peptide present, claims require that there be a “therapeutically effective amount.” This is defined on page 4 of the application as being an amount sufficient to reduce oxidative cellular damage that may be associated with a variety of specific conditions, including stroke, heart attack, spinal injury and surgery. Thus, the conditions for which pharmaceutical compositions are to be administered are clearly defined in the application as is the therapeutic objective, *i.e.*, to prevent oxidative damage. Additional guidance is provided by indicating that a typical therapeutically effective dose will be between 0.01 and 10 mg of peptide per day. In light of these teachings, Applicant submits that all of the terms used in claims have been clearly defined in the specification and that the claims comply with the requirements of 35 U.S.C. § 112, second paragraph. It is therefore respectfully requested that the Examiner’s rejection be withdrawn.

Conclusion

In light of the amendments and discussion above, Applicant believes that the claims now pending in the application should be allowable. Early notice to this effect is earnestly solicited.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (202)419-7013.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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09/978,178

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rogers, Jack
Appl. No.: 09/978,178
Filed: October 17, 2001
For: **Peptides Derived from the Human Amyloid Precursor Protein**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION (37 C.F.R. § 1.63) AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the application identified above.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 C.F.R. § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119, of any United States provisional applications or foreign application(s) for patent or inventor's certificate or of any PCT International Application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International Application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application on which priority is claimed:

<u>Application Serial No.</u>	<u>Country</u>	<u>Filing Date (Day/Month/Year)</u>	<u>Priority Claimed (Yes/No)</u>
60/243,403	United States	October 27, 2000	Yes

I hereby claim the benefit under Title 35, United States Code, Section 120, of any United States application(s) or PCT International Application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56, which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status (Patented, Pending, Abandoned)</u>
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

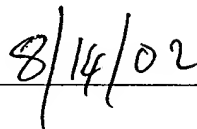
I hereby appoint Romi N. Bose, Reg. No. 43,322; Kendrew H. Colton, Reg. No. 30,368; Francis A. Even, Reg. No. 16,880; Stephen S. Favakeh, Reg. No. 36,798; Karl R. Fink, Reg. No. 34,161; Morgan L. Fitch, Jr., Reg. No. 17,023; John F. Flannery, Reg. No. 19,759; Robert J. Fox, Reg. No. 27,635; James J. Hamill, Reg. No. 19,958; Mark W. Hetzler, Reg. No. 38,183; Ramon R. Hoch, Reg. No. 34,108; Perry J. Hoffman, Reg. No. 37,150; Robert B. Jones, Reg. No. 20,135; Richard A. Kaba, Reg. No. 30,562; James P. Kreuger, Reg. No. 35,234; Thomas F. Lebens, Reg. No. 38,221; Timothy E. Levstik, Reg. No. 30,192; Timothy P. Maloney, Reg. No. 38,233; Bruce R. Mansfield, Reg. No. 29,086; Steven G. Parmelee, Reg. No. 28,790; Philip T. Petti, Reg. No. 31,651; Kathleen A. Ranney, Reg. No. 37,702; Kenneth H. Samples, Reg. No. 25,747; Michael A. Sanzo, Reg. No. 36,912; James J. Schumann, Reg. No. 20,856; Joseph E. Shipley, Reg. No. 31,137; Julius Tabin, Reg. No. 16,754; and Richard E. Wawrzyniak, Reg. No. 36,048, all registered to practice before the Patent and Trademark Office, as my attorneys with full power of substitution and revocation to prosecute this application and all divisions and continuations thereof and to transact all business in the Patent and Trademark Office connected therewith and request that all correspondence and telephone communications be directed to the following person(s) at the mailing address and telephone number hereafter given:

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